ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

April 3, 2008

The Honorable Andrew von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

We are troubled by the February 1, 2008, response by the Food and Drug Administration (FDA) to the November 14, 2007, letter from Ranking Member Joe Barton and then Subcommittee Ranking Member Ed Whitfield regarding FDA's enforcement priorities and dispute resolution process.

FDA's response did not deal with two important policy issues raised in the November 14, 2007, letter: (1) Preventing regulatory disputes from escalating by getting early top-management intervention; and, (2) Engaging in good-faith dispute resolution. The FDA has in effect defended a practice of telling a company that it could appeal a decision when in fact FDA intended to proceed with an enforcement action against the company; FDA would actually use the intervening time before responding to the appeal request to prepare the enforcement action. We do not believe there is ever a situation where the FDA should be given a license to lie to regulated industry.

We are also disappointed in the February 1, 2008, response because we do not believe this is an accurate reflection of your leadership and the way you would want the FDA to conduct itself in its dealings with regulated industry. We would very much appreciate you meeting with us to assure us that you share our perspective on appropriate FDA enforcement priorities and dispute resolution processes. In light of an upcoming April 22 hearing on FDA resources, we would like this meeting to be held prior to that hearing.

Thank you for your attention to this request.

Sincerely,

Joe Barton
Ranking Member

John Shimkus
Ranking Member
Subcommittee on Oversight & Investigations

cc: John D. Dingell, Chairman
Committee on Energy and Commerce
Bart Stupak, Chairman
Subcommittee on Oversight and Investigations